UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	Master Docket: No. 21-mc-1230-JFC MDL No. 3014
This document relates to: PHILIPS RS NORTH AMERICA LLC and PHILIPS NORTH AMERICA LLC, *Plaintiffs*, v. PSN LABS, LLC, *Defendant*.	No. 2:24-cv-01077

ANSWER AND AFFIRMATIVE DEFENSES TO COMPLAINT

AND NOW, comes defendant, PSN Labs, LLC, by and through its attorneys, MacDonald, Illig, Jones & Britton, LLP, and files this Answer and Affirmative Defenses to the Complaint, stating the following in support:

ANSWER

INTRODUCTION

1. Paragraph 1 is denied. In further response, pursuant to PSN Labs, LLC's ("PSN Labs") review of various documents and communications, Philips RS North America, LLC ("Philips RS") and/or Philips North America LLC ("Philips NA") (collectively, "Philips" or "Plaintiffs") as early as 2016 began investigating degradation of the polyester-based polyurethane

("PE-PUR") foam in Philips' sleep and respiratory care devices. In 2018, Philips RS initiated testing to study the PE-PUR foam, and received results classified as failing. Specifically, three substances were identified: formaldehyde; Phenol, 2,6-bis; and benzoic acid-ethoxy-,ethyl ester. PSN Labs, following its engagement over two years later, identified two of these three substances with results classified as not meeting the requirements of ISO 18562-1:2017 or ISO 18652-1:2024, which required additional analysis for hazard characterization and rendered PSN Labs unable to write a successful risk assessment for Philips devices containing PE-PUR.

The testing PSN Labs conducted had nothing to do with how Philips sleep and respiratory care devices behaved over time (*i.e.*, the foam degradation), which was the issue that led to the Class I June 2021 recall as acknowledged by Philips' CEO. Philips consistently used the results of PSN Labs testing on out-of-the-box (*i.e.*, new) units to support its position, which conflates PSN Labs testing with the foam degradation issue that actually led to the recall. Philips has acknowledged, and the U.S. Food and Drug Administration (FDA) has agreed, that the PE-PUR foam found in Philips' devices degrades over time and "can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment." Further, the FDA cited, and again Philips agreed, that Philips failed to follow required processes to deliver the devices to consumers. Instead of addressing these errors and moving forward, Philips has continued to mischaracterize testing results in an effort to conceal the ultimate foam degradation issue. Philips, similar to its attempts against other third parties, is attempting to deflect attention to PSN Labs and away from Philips' own failures, negligence, concealment, and recklessness.

2. Paragraph 2 is admitted in part and denied in part. It is admitted that, at Philips' request, Philips NA and PSN Labs, then known as Advanced Solutions Network, LLC, executed a Quality Agreement dated July 31, 2019 (the "2019 Quality Agreement"), for services identified

in Philips' General Conditions of Purchase, Version May 2018, related to Philips' manufacturing, distribution, and/or commercialization of medical device products. PSN Labs offers, as one of multiple service lines, ISO-accredited testing of materials and products.

The remainder of Paragraph 2 is denied. PSN Labs was certified to ISO 18562-3:2017 standards on March 20, 2019, and thereafter engaged with Philips RS on potential ISO 18562 work. Philips held multiple meetings, including two on-site inspections of PSN Labs, prior to the parties' initial proposal for ISO 18562 testing dated December 28, 2020 related to devices containing PE-PUR foam. Further, the 2019 Quality Agreement is a written document that speaks for itself, and PSN Labs denies any interpretation and/or characterization of its contents that is inconsistent with its express provisions.

3. Paragraph 3 is admitted in part and denied in part. It is admitted that, following Philips' purchase order, PSN Labs submitted to Philips several proposals between December 2020 and July 2021 for various scopes of work related to ISO 18562 testing of Philips' sleep and respiratory care devices containing PE-PUR foam. It is further admitted that Matthew Heidecker, Ph.D. was the Project Manager under each Philips' proposal.

The remainder of Paragraph 3 is denied. In further response, Philips failed to communicate whether the device testing to be conducted by PSN Labs was for purposes of 510k clearance, post-market risk assessment (PMRA), to inform a corrective and preventative action plan or CAPA (which was in fact the case and had been active since 2019), or otherwise. ***Philips' claims against PSN Labs fail*** because, by January 2021, Philips had already determined through *in vitro* assays that the degraded foam was mutagenic. In addition, testing by other facilities prior to PSN Labs' work confirmed that the PE-PUR foam failed genotoxicity and volatile organic compound (VOC) testing. These genotoxicity and VOC test results alone should have been enough to trigger a recall of on-market devices -- but Philips failed to move forward with same. Further, Philips'

acknowledged to the public in its Q1 2021 Quarterly Report that the company had identified "possible risks" associated with "the sound abatement foam," specifically, foam degradation. PSN Labs consistently advised Philips that clarity on the time duration of PE-PUR foam degradation was critical for PSN Labs to complete a full risk assessment according to ISO 10993-17. In response, Philips advised PSN Labs that Philips did not want to create more negative paperwork by conducting more testing. Accordingly, PSN Labs did not opine as to whether Philips' devices containing PE-PUR would meet the FDA requirements for biological safety according to ISO 10933.

4. Paragraph 4 is denied. In further response, PSN Labs did not commit "egregious errors" in any testing and/or associated analysis as alleged by Philips. Prior to PSN Labs' work for Philips RS, Philips was already internally aware of consumer complaints (approximately 222,000 such complaints, per the FDA's findings); had identified risks associated with Philips' sleep and respiratory care devices as communicated by internal Philips' employees and third-party testing facilities; and the Department of Justice's investigation had already commenced. ***Quite simply, prior to PSN Labs' work, Philips was aware that a recall of its sleep and respiratory care devices was necessary.*** PSN Labs essentially provided one report, which pales in comparison to the dozens of *in vivo* and *in vitro* assays that Philips has run on degraded and exemplar PE-PUR foam, most of which failed the requirements of the ISO standard. PSN Labs' one report is not the reason or the basis for the Philips recall. Philips had been researching the issue since at least 2016 and did not engage PSN Labs to test PE-PUR devices (*i.e.*, DreamStation) until 2021. PSN Labs did not issue its initial draft report (early, at Philips' insistence) until March 2021. PSN Labs testing report conclusions were clear and repeatedly identified hazards that could not be characterized and/or recommended additional testing to confirm any findings. PSN Labs also indicated that the device, and more specifically the PE-PUR foam within, is known to break down over time (although what

time period was not clear, and Philips declined further testing to identify same). Further, given the known foam degradation, PSN Labs could not report the device was "safe" in conformance with ISO standards, which require that the device be biologically safe across its lifetime.

VOC Testing/Dimethyl Diazene - Volatile organic compound (VOC) testing is governed by ISO 18562, which was formally adopted in 2017. This test requires the collection and analysis of substances considered to be VOCs. PSN Labs and other similarly accredited facilities use three techniques for VOC testing: targeted high-pressure liquid chromatography (HPLC), discovery, and targeted GC-MS (Gas Chromatography, Mass-Spectrometry). PSN Labs screened for VOCs in Philips' device via GC-MS, and dimethyl diazene was detected as a "tentative" assignment. A tentative identification means that data has been obtained that is consistent with a class of molecule, not a specific one. No reference standard was available to confirm the assessment, and out of an abundance of caution, PSN Labs identified the tentative VOC and concluded additional testing was necessary to confirm its presence. Philips refused additional testing. Regardless, PSN Labs' tentative identification of dimethyl diazene does not/did not change the outcome or otherwise enable PSN Labs to prepare a full risk assessment according to ISO 10993-17, which it was unable to do given the PE-PUR foam degradation. Further, PSN Labs' tentative identification of dimethyl diazene paled in comparison to the patient safety risk of Phenol, 2,6-bis.

Ozone - As required by ISO 18562-1:2017, PSN Labs utilized calibrated chemical indicating sensors to test for inorganic gases and detected ozone on the sensor on March 17, 2021. PSN Labs reported this result to Philips; there was no interpretation of the result provided by PSN Labs. Via conference call, Philips

requested that PSN Labs omit the ozone finding as it was "inconvenient," and PSN Labs refused to do so. In one study alone, PSN Labs tested 26 Philips devices containing PE-PUR foam, and ozone via the chemical indicating sensor was detected in seven, or approximately 27% of the devices. These findings were confirmed by three different sensors and reported as either ozone or a chemical interference detected as ozone output.

Risk assessment - PSN Labs clearly and consistently stated in its reports that no laboratory or toxicologist can write a risk assessment for a device with PE-PUR foam that is known to degrade in the field without an understanding of when and under what circumstances that degradation begins and how it degrades over time. PSN Labs also clearly and consistently stated that the hazards had not been fully characterized. Stating otherwise would potentially have made PSN Labs a subject of the Department of Justice investigation along with Philips.

Phenol, 2,6-bis - Again, PSN Labs clearly and consistently advised Philips that the manner of testing for the devices was not analogous to how the devices operated in real-life, and that various testing times may lead to different VOC profiles. The finding of Phenol, 2,6-bis alone, pursuant to ISO standards, is indicative of potential risk to the patient that outweighs any noise abatement benefit of the PE-PUR foam component.

Quite simply, from PSN Labs' perspective, the data is the data, and what a client chooses to do with same is at their discretion. In the underlying matter, Philips had discretion to heed PSN Labs' report and conduct further testing, but Philips declined and continued to conceal the defective nature of its sleep and respiratory care devices. Regardless, it did not matter what PSN Labs' data revealed, because Philips already knew a recall was necessary.

5. Paragraph 5 is denied. In further response, see Paragraph 4, above. Further, PSN Labs' conclusions were simple: the hazards had not been fully characterized and thus PSN Labs recommended additional testing. Specifically, PSN Labs recommended testing outside the scope of a biocompatibility test to ensure PSN Labs could share more information and remain impartial. Philips, repeatedly, refused. PSN Labs had nothing to hide and consistently delivered the same message to Philips throughout the parties' relationship: PSN Labs would not and could not write a successful risk assessment for the PE-PUR foam. Further, it is Philips, not PSN Labs, who covered up its mistakes by masking, skewing, and cherry-picking favorable test results in efforts to minimize and hide from the public and regulatory bodies (*e.g.*, FDA, TUV, etc.) significant risks that had long been known to Philips.

6. Paragraph 6 is denied. In further response, PSN Labs provided to Philips all data as required by FDA reporting and in accordance with ISO/IEC 17025 compliance. At the request of Philips, PSN Labs provided additional data outside the scope of that required under PSN Labs' proposal and corresponding statements of work. Philips had and has no rights to further raw data pursuant to the terms of the 2019 Quality Agreement nor is providing such data standard practice within the industry. Further, the requests for this raw data were communicated to PSN Labs in such a manner that PSN Labs felt pressure from Philips to change and/or revise previously authored reports, which would have been a fundamental violation of the quality principles to which PSN Labs has and will continue to hold itself. PSN Labs refused to make available data that could compromise PSN Labs' independence and accreditation, which is predicated on demonstrable proof that no external sponsor influences the outcomes of tests or evaluations. Specifically, Section 5.1 of the 2019 Quality Agreement requires PSN Labs to conduct all Philips testing in accordance with ISO/IEC 17025, which in turn mandates that PSN Labs evaluate risks to impartiality on an on-going basis. PSN Labs encountered numerous red flags during Philips'

repeated requests for the raw data that led PSN Labs to suspect that Philips might use the raw data to pressure PSN Labs to modify its report. Accordingly, PSN Labs denied Philips' raw data requests to preserve the impartiality of PSN Labs' test reports and remain compliant with ISO/IEC 17025. Per the 2019 Quality Agreement, this mandate took precedence over any assertion that Philips was contractually entitled to the raw data. Further, Philips has admitted (on its own website) that it has worked with independent laboratories to harmonize testing thresholds -- exactly the type of action that PSN Labs refused to engage in, as harmonization is in violation of ISO standards.

With respect to Shayne Gad, Ph.D., a nationally recognized expert on toxicology, PSN Labs retained Dr. Gad in June 2021 *after* obtaining approval from Philips to do so. Dr. Gad reviewed and provided commentary on the findings of three independent laboratories: PSN Labs, UL, and Intertek. Dr. Gad's conclusion was simple: the device should not be sold with the PE-PUR foam. With respect to his review of PSN Labs, Dr. Gad confirmed PSN Labs' assessment of dimethyl diazene. While Dr. Gad suggested that the toxicology threshold of concern for Phenol, 2,6-bis was different than that identified by PSN Labs, the tested device nevertheless failed under the recalculated threshold. Critically, Dr. Gad determined the PE-PUR foam was genotoxic, one of the most serious failings.

7. Paragraph 7 is denied. In further response, as early as 2016, Philips knew of the PE-PUR foam degradation issue yet failed to proceed with efforts to review same until more than five years later. Further, and as mentioned above, a risk assessment suggesting safety ***cannot*** be completed for a device known to degrade in the field without knowing when and how the degradation occurs.

8. Paragraph 8 is denied. In further response, Philips had more than five years from the time of the first documented instances of degradation to assess the risk, but instead spent those years answer shopping in efforts to avoid publicly revealing an obvious hazard. No later than

2020, and still prior to PSN Labs' work, Philips' own employees recognized this issue and were calling for a recall.

9. Paragraph 9 is denied. In further response, see Paragraphs 4 through 8, above. Further, if Philips sustained damages by reason of the matters alleged in the Complaint, which is denied, then said damages were caused in whole or in part by Philips' own breach of contract and/or Philips' failure to properly manage its product line, and were not caused or contributed to in any manner by any alleged fault, breach of contract, breach of warranty, or negligence of PSN Labs, its officers, agents, contractors, servants, employees, or others for whom it was responsible.

PARTIES

10. PSN Labs lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 10 and, on that basis, denies them.

11. PSN Labs lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 11 and, on that basis, denies them.

12. Paragraph 12 is admitted. In further response, effective November 2, 2023, Advanced Solutions Network, LLC was amended to PSN Labs, LLC, a Pennsylvania limited liability company with a principal place of business in Erie, Pennsylvania.

JURISDICTION AND VENUE

13. Paragraph 13 is admitted in part and denied in part. PSN Labs lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraphs 15 and 16, below, and, on that basis, denies them and the resulting legal conclusion of diversity. However, assuming diversity of citizenship, it is admitted that this Court has jurisdiction pursuant to 28 U.S.C. § 1332.

14. Paragraph 14 is admitted.

15. PSN Labs lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 15 and, on that basis, denies them.

16. PSN Labs lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 16 and, on that basis, denies them.

17. Paragraph 17 is admitted.

18. Paragraph 18 is admitted. In further response, the Western District of Pennsylvania has personal jurisdiction over PSN Labs pursuant to Federal Rule of Civil Procedure 4(k) and Pennsylvania's long-arm statute, 42 Pa. Cons. Stat. § 5322.

19. Paragraph 19 is admitted. In further response, pursuant to Philips' General Conditions of Purchase, Version May 2018, the parties consented to the personal jurisdiction of courts of the Commonwealth of Pennsylvania.

20. Paragraph 20 is admitted. In further response, venue is proper in the Western District of Pennsylvania pursuant to the terms of the 2019 Quality Agreement, Philips' General Conditions of Purchase, Version May 2018, and 28 U.S.C. § 1391.

FACTUAL BACKGROUND

21. PSN Labs lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 21 and, on that basis, denies them. Further, Paragraph 21 states expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied.

22. Paragraph 22 is admitted in part and denied in part. It is admitted that part of PSN Labs' scope of work for Philips included testing of specific devices related to the PE-PUR foam, and ozone impact on the foam's degradation. The remainder of Paragraph 22 is denied. In further

response, prior to PSN Labs' work for Philips, Philips was already internally aware of voluminous consumer complaints, had already identified risks associated with its sleep and respiratory care devices as communicated by Philips employees and third-party testing facilities, and the Department of Justice's investigation had already commenced. Quite simply, prior to PSN Labs' work, Philips was aware that a recall of its sleep and respiratory care devices was necessary. PSN Labs' first ISO 18562 test of the PE-PUR foam in a specific device was not until March 2021, and despite Philips' internal knowledge, PSN Labs was not informed of the reason for the test. PSN Labs was requested by Philips to perform a standard test to determine whether a patient could be exposed to hazardous amounts of VOCs, but PSN Labs was not advised at the time of this request that PSN Labs' testing was in any way related to a possible recall or an assessment of risk of units presently in the field.

I. PSN Labs' Engagement

23. Paragraph 23 is denied. In further response, it was Philips who first approached PSN Labs at an industry tradeshow, and PSN Labs completed a small, introductory project (unrelated to the devices recalled) for Philips in 2018. In June 2018, PSN Labs was invited to the Philips facilities to conduct a capabilities presentation. Over the next several months, PSN Labs worked to understand Philips' needs, and ISO 18562 testing was one of those needs, specifically without background contamination concerns. PSN Labs was not aware of the specific consumer complaints, internal investigations, and/or specific scope of work requests related to PE-PUR foam degradation and/or VOC exposures.

24. Paragraph 24 is admitted in part and denied in part. It is admitted that Philips NA and PSN Labs, then known as Advanced Solutions Network, LLC, executed the 2019 Quality Agreement. The remainder of Paragraph 24 is denied. In further response, prior to execution of the 2019 Quality Agreement, Philips performed a site audit at PSN Labs, during which Philips'

auditor had full access to PSN Labs' facility, quality management systems, equipment, documents, and staff qualifications, and Philips noted zero non-conformances, corrective action requests, and/or opportunities for improvement. Further, the 2019 Quality Agreement is a written document that speaks for itself, and PSN Labs denies any interpretation and/or characterization of its contents that is inconsistent with its express provisions. Further, Paragraph 24 contains a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, those averments are specifically denied.

25. Paragraph 25 is denied. In further response, Philips failed to abide by the provisions of the 2019 Quality Agreement by failing to articulate and/or otherwise disclose the reasons for testing of the PE-PUR foam. Further, the 2019 Quality Agreement is a written document that speaks for itself, and PSN Labs denies any interpretation and/or characterization of its contents that is inconsistent with its express provisions. Further, Paragraph 25 contains conclusions of law to which no response is necessary. To the extent that a response is deemed necessary, those averments are specifically denied.

26. Paragraph 26, inclusive of subparagraphs (a) through (c), is denied. In further response, prior to execution of the 2019 Quality Agreement, Philips performed a site audit at PSN Labs, during which Philips' auditor had full access to PSN Labs' facility, quality management systems, equipment, documents, and staff qualifications, and Philips noted zero non-conformances, corrective action requests, and/or opportunities for improvement. Further, the 2019 Quality Agreement's reference to ISO 13485, Section 7.6 is invalid as it relates to PSN Labs' recordkeeping, which is governed by PSN Labs' accreditation under ISO/IEC 17025: 2017. Further, PSN Labs was advised by its accreditor (Perry Johnson Laboratory Accreditation, Inc. ["PJLA"]) that any further transfer of information (the "raw data" as alleged in Philips' Complaint) would be an infringement of clause 4.1 of ISO/IEC 17025:2017 related to impartiality. Further,

the 2019 Quality Agreement is a written document that speaks for itself, and PSN Labs denies any interpretation and/or characterization of its contents that is inconsistent with its express provisions. Further, Paragraph 26 contains conclusions of law to which no response is necessary. To the extent that a response is deemed necessary, those averments are specifically denied. It is further denied that PSN Labs in any way failed to perform in accordance with the parties' Quality Agreement. It is further denied that the alleged breach by PSN Labs of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof is demanded at the time of trial. In further response, Philips' inclusion of footnotes throughout the Complaint does not comply with Federal Rule of Civil Procedure 10(b), requiring that allegations be stated "in Numbered paragraphs, each limited as far as practicable to a single set of circumstances." As such, no response is required to the footnotes, and they would be properly stricken. *See Holmes v. Gates*, 2010 WL 956412, at *1 (M.D. Pa. Mar. 11, 2010), *aff'd.* 403 F. App'x 670 (3d Cir. 2010). To the extent that any response to footnote 1 of Paragraph 25 is required, the averment contained within the footnote is admitted.

II. Philips' Improper Allegation of PSN Labs' Reckless and Grossly Negligent Conduct

27. Paragraph 27 is denied. In further response, there was never communication from Philips as to the purpose of the requested testing, *e.g.*, what it would be used for and/or how it would impact any recall. Philips did not advise PSN Labs that Philips was considering any recall until after PSN Labs provided initial reports at the end of April 2021. Further, had Philips communicated to PSN Labs the purpose for the testing, PSN Labs would have declined the work as PSN Labs was not then nor was it ever able to complete a full risk assessment according to ISO 10993-17 independent of the testing outcome. Further, the 2019 Quality Agreement and Philips' purchase orders for testing services are written documents that speak for themselves, and PSN

Labs denies any interpretation and/or characterization of their contents that is inconsistent with their express provisions. Further, Paragraph 27 contains conclusions of law to which no response is necessary. To the extent that a response is deemed necessary, those averments are specifically denied. It is further denied that PSN Labs in any way failed to perform in accordance with the 2019 Quality Agreement. It is further denied that the alleged breach of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof is demanded at the time of trial.

A. Philips' Improper Allegations of PSN Labs' Mistaken Detection of Dimethyl Diazene

28. Paragraph 28 is denied. In further response, PSN Labs' conclusions were simple: the devices' hazards had not been fully characterized. PSN Labs recommended additional testing to inform any risk assessment, but Philips repeatedly refused. In further response, Philips' inclusion of footnotes throughout the Complaint does not comply with Federal Rule of Civil Procedure 10(b), requiring that allegations be stated "in Numbered paragraphs, each limited as far as practicable to a single set of circumstances." As such, no response is required to the footnotes, and they would be properly stricken. *See Holmes v. Gates*, 2010 WL 956412, at *1 (M.D. Pa. Mar. 11, 2010), *aff'd.* 403 F. App'x 670 (3d Cir. 2010). To the extent that any response to footnote 2 of Paragraph 28 is required, the averment contained within the footnote is admitted.

29. Paragraph 29 is denied. In further response, PSN Labs' conclusions were simple: the devices' hazards had not been fully characterized. PSN Labs recommended additional testing to inform any risk assessment, but Philips repeatedly refused. Further, the revision (Rev D) to PSN Labs' report was at the request of and incorporated the comments of Philips' contract toxicologist, who in January 2021 agreed that the degraded PE-PUR foam was not biocompatible to take "a more aggressive stance" on dimethyl diazene in the direction of patient safety. This was a clear

implication by Philips' contract toxicologist, *prior to* PSN Labs' engagement, that Philips devices containing PE-PUR foam needed to be recalled.

B. PSN Labs' Expedited VOC Testing

30. Paragraph 30 is denied. In further response, Philips again mischaracterizes the issue, which relates to degraded (not pristine) foam complaints well prior to PSN Labs' testing of the devices at issue. Further, the multiple revisions to PSN Labs' Report were all at the request of Philips: Rev A was requested by Philips to see preliminary results; Rev B was a preliminary report requested by Philips "as soon as humanly possible"; Rev C was requested by Philips to reduce the use exposure, in contravention to FDA-accepted modulation (at issue in the ultimate recall, but further conflated by Philips extrapolating new PE-PUR foam results to degraded results); Rev D was requested by Philips' contract toxicologist to take a "more aggressive stance" on dimethyl diazene (the first time dimethyl diazene was at issue because PSN Labs had initially passed dimethyl diazene as "tentative" in Rev C); Rev E included the full VOC profile (which included Phenol, 2,6-bis) as part of PSN Labs' normal reporting profile; Rev F to build a multipoint standard curve to quantify Phenol, 2,6-bis (although Philips' requested time of exposure -- 8 hours versus 24 hours -- made little sense); and Rev G at the request of Philips to separate risks into "acute" versus "chronic." None of the requested revisions changed the overall outcome. In further response, Philips' inclusion of footnotes throughout the Complaint does not comply with Federal Rule of Civil Procedure 10(b), requiring that allegations be stated "in Numbered paragraphs, each limited as far as practicable to a single set of circumstances." As such, no response is required to the footnotes, and they would be properly stricken. *See Holmes v. Gates*, 2010 WL 956412, at *1 (M.D. Pa. Mar. 11, 2010), *aff'd.* 403 F. App'x 670 (3d Cir. 2010). To the extent that any response to footnote 3 of Paragraph 30 is required, the averment contained within the footnote is admitted.

31. Paragraph 31 is denied. In further response, as required by ISO 18562-1:2017, PSN Labs utilized calibrated chemical indicating sensors for testing of inorganic gases and detected ozone on the sensor on March 17, 2021. PSN Labs reported this result to Philips; there was no interpretation of the result provided by PSN Labs. Via conference call, Philips requested that PSN Labs omit the ozone finding as it was inconvenient, and PSN Labs refused to do so. In one study alone, PSN Labs tested 26 Philips' devices containing PE-PUR foam, and ozone was detected by chemical indicating sensors in seven, or approximately 27% of the devices. This result was confirmed by three different sensors and reported as either ozone or a chemical interference detected as ozone. PSN Labs reported that, in either scenario, VOC testing was not capturing the full extent of risk to patient safety. In further response, Philips' inclusion of footnotes throughout the Complaint does not comply with Federal Rule of Civil Procedure 10(b), requiring that allegations be stated "in Numbered paragraphs, each limited as far as practicable to a single set of circumstances." As such, no response is required to the footnotes, and they would be properly stricken. *See Holmes v. Gates*, 2010 WL 956412, at *1 (M.D. Pa. Mar. 11, 2010), *aff'd.* 403 F. App'x 670 (3d Cir. 2010). To the extent that any response to footnote 4 of Paragraph 31 is required, the averment contained within the footnote is admitted.

32. Paragraph 32 is denied. In further response, the multiple revisions were all at the request of Philips: Rev A was requested by Philips to see preliminary results; Rev B was a preliminary report requested by Philips "as soon as humanly possible"; Rev C was requested by Philips to reduce the use exposure, in contravention to FDA-accepted modulation (at-issue in the ultimate recall, but further conflated by Philips extrapolating new PE-PUR foam results to degraded results); Rev D was requested by Philips' contract toxicologist to take a "more aggressive stance" on dimethyl diazene (the first time dimethyl diazene was at issue because PSN Labs had initially passed dimethyl diazene as "tentative" in Rev C); Rev E included the full VOC profile

(which included Phenol, 2,6-bis) as part of PSN Labs' normal reporting profile; Rev F at the request of Philips to build a multipoint standard curve to properly quantify Phenol, 2,6-bis; and Rev G at the request of Philips to separate risks into "acute" versus "chronic." None of the requested revisions changed the overall outcome. None of the requested revisions constituted a full risk assessment according to ISO 10993-17. None of the requested revisions impacted the recall, which was due to PE-PUR foam degradation.

33. Paragraph 33 is denied. In further response, the multiple revisions were all at the request of Philips: Rev A was requested by Philips to see preliminary results; Rev B was a preliminary report requested by Philips "as soon as humanly possible"; Rev C was requested by Philips to reduce the use exposure, in contravention to FDA-accepted FDA modulation (at-issue in the ultimate recall, but further conflated by Philips extrapolating new PE-PUR foam results to degraded results); Rev D was requested by Philips' contract toxicologist to take a "more aggressive stance" on dimethyl diazene (the first time dimethyl diazene was at issue because PSN Labs had initially passed dimethyl diazene as "tentative" in Rev C); Rev E included the full VOC profile (which included Phenol, 2,6-bis) as part of PSN Labs' normal reporting profile; Rev F at the request of Philips to build a multipoint standard curve to properly quantify Phenol, 2,6-bis; and Rev G at the request of Philips to separate risks into "acute" versus "chronic." None of the requested revisions changed the overall outcome. None of the requested revisions constituted a full risk assessment according to ISO 10993-17. None of the requested revisions impacted the recall, which was due to PE-PUR foam degradation. Further, the finding of Phenol, 2,6-bis, alone, pursuant to ISO standards is indicative of potential risk to the patient that outweighs any benefit of the PE-PUR foam component. Further, Philips has acknowledged (on its own website) that it has worked with independent laboratories to harmonize thresholds, which is in violation of ISO standards. Even setting all of the above aside, the fact remains that the PE-PUR foam degrades, which is the

cause of the recall -- regardless of any initial emission that had not been fully characterized by PSN Labs. In further response, Philips' inclusion of footnotes throughout the Complaint does not comply with Federal Rule of Civil Procedure 10(b), requiring that allegations be stated "in Numbered paragraphs, each limited as far as practicable to a single set of circumstances." As such, no response is required to the footnotes, and they would be properly stricken. *See Holmes v. Gates*, 2010 WL 956412, at *1 (M.D. Pa. Mar. 11, 2010), *aff'd.* 403 F. App'x 670 (3d Cir. 2010). To the extent that any response to footnotes 5 and 6 of Paragraph 33 is required, the averments contained within those footnotes are admitted in part and denied in part. In further response, footnote 5 is admitted. Footnote 6 is denied. In further response, Philips continually failed to consider all published research on Phenol, 2,6-bis, which is exemplified in Philips' summation, assumptions, and references as set forth in footnote 6.

34. Paragraph 34 is denied. In further response, PSN Labs used multiple methods to risk assess Phenol, 2,6-bis, and in Rev E showed the progression of calculations as PSN Labs conducted additional research on the molecule -- as PSN Labs' report confirms, "multiple conservative methods were used to risk assess the Phenol, 2,6-bis." PSN Labs did not report that Phenol, 2,6-bis was "mutagenic" or "a mutagen." What PSN Labs did report was that this specific molecule has a piece of its chemistry (its actual structure) that in many other molecules has caused those molecules to be genotoxic and/or mutagenic. Meaning, from a toxicological weight of evidence approach, classifying and risk assessing the molecule as having the potential to be genotoxic and/or mutagenic with accompanying appropriate thresholds is the proper course of action.

35. Paragraph 35 is denied. In further response, PSN Labs labeled Phenol, 2,6-bis as a hazard that "had not been characterized" and suggested additional testing, but Philips repeatedly

refused. PSN Labs' conclusion and recommendation is the same conclusion and recommendation reached by the FDA.

C. PSN Labs' Run-In Report

36. Paragraph 36 is denied. In further response, this allegation confirms Philips' continued vacillation between trying to identify risks and refuting findings by testing facilities with which Philips disagreed -- neither of which Philips communicated to PSN Labs when PSN Labs commenced its testing. Further, PSN Labs' work was testing of "new" devices as opposed to those already in the field, which Philips further conflated by extrapolating new PE-PUR foam results to degraded results. PSN Labs could not and did not write a successful risk assessment for the PE-PUR foam. PSN Labs clearly communicated this limitation to Philips on or before April 8, 2021. PSN Labs made no mistakes, and PSN Labs did not provide toxicological conclusions as doing so would have been inappropriate.

37. Paragraph 37 is denied. In further response, this allegation confirms Philips' continued vacillation between trying to identify risks and refuting findings by testing facilities with which Philips disagreed -- neither of which was communicated to PSN Labs when it commenced its testing. Further, PSN Labs tested "new" devices as opposed to those already in the field -- which was further conflated by Philips extrapolating new PE-PUR foam results to degraded results. PSN Labs could not and did not write a successful risk assessment for the PE-PUR foam. PSN Labs clearly communicated this limitation to Philips on or before April 8, 2021. PSN Labs made no mistakes, and PSN Labs did not provide toxicological conclusions as doing so would have been inappropriate.

38. Paragraph 38 is denied. In further response, this allegation confirms Philips' continued vacillation between trying to identify risks and refuting findings by testing facilities with

which Philips disagreed -- neither of which was communicated to PSN Labs when it commenced its testing. Further, PSN Labs tested "new" devices as opposed to those already in the field, which was further conflated by Philips extrapolating new PE-PUR foam results to degraded results. PSN Labs could not and did not write a successful risk assessment for the PE-PUR foam. PSN Labs clearly communicated this limitation to Philips on or before April 8, 2021. PSN Labs made no mistakes, and PSN Labs did not provide toxicological conclusions as same were inappropriate.

III. The Recall

39. Paragraph 39 is denied. In further response, PSN Labs entirely refutes any allegation that PSN Labs claimed that VOCs could not be stopped by a filter, although it is PSN Labs' opinion that such a proposal is illogical for the devices containing PE-PUR as any filter usage would need to be supported by research. This was communicated to Philips, which chose to do nothing. Further, PSN Labs was one of multiple laboratories with findings that Philips devices failed VOC tests, the first of which was in 2019, two years prior to PSN Labs' work.

40. Paragraph 40 is denied. In further response, this allegation confirms Philips' continued vacillation between trying to identify risks and refuting findings by testing facilities with which Philips disagreed -- neither of which was communicated to PSN Labs when it commenced its testing. Further, PSN Labs tested "new" devices as opposed to those already in the field, which was further conflated by Philips extrapolating new PE-PUR foam results to degraded results. PSN Labs could not and did not write a successful risk assessment for the PE-PUR foam. PSN Labs clearly communicated this limitation to Philips on or before April 8, 2021. PSN Labs made no mistakes, and PSN Labs did not provide toxicological conclusions as same were inappropriate.

41. Paragraph 41 is denied. In further response, this allegation confirms Philips' continued vacillation between trying to identify risks and refuting findings by testing facilities with

which Philips disagreed -- neither of which was communicated to PSN Labs when it commenced its testing. Further, PSN Labs tested "new" devices as opposed to those already in the field, which was further conflated by Philips extrapolating new PE-PUR foam results to degraded results. PSN Labs could not and did not write a successful risk assessment for the PE-PUR foam. PSN Labs clearly communicated this limitation to Philips on or before April 8, 2021. PSN Labs made no mistakes, and PSN Labs did not provide toxicological conclusions as same were inappropriate. Further, Philips has, for over three years, tried to walk back the recall, but has been rejected by the FDA in each attempt to do so, with the FDA stating on May 2, 2022, that it disagreed with Philips' reclassification of risks and that the approach Philips attempted to state was unsafe.

42. Paragraph 42 is denied. In further response, Philips' recall was due to the fact that the PE-PUR foam degrades as a function of normal use (*i.e.*, during the device's useful life), and not concerns about VOCs in the as-manufactured state (*i.e.*, beginning of life). If Philips was concerned about the VOCs in new devices, Philips would have recalled these devices in 2019 (prior to PSN Labs' engagement and work) after the initial testing highlighted severe concerns and the devices failed VOC tests.

IV. PSN Labs' Improperly Alleged Post-Recall Misconduct

43. Paragraph 43 is denied. In further response, Philips recall was due to the fact that the PE-PUR foam degrades as a function of normal use (*i.e.*, during the device's useful life), and not concerns about VOCs in the as-manufactured state (*i.e.*, beginning of life). If Philips was concerned about the VOCs in new devices, Philips would have recalled these devices in 2019 (prior to PSN Labs' engagement and work) after the initial testing highlighted severe concerns and failed VOC tests.

A. PSN Labs' Outside Toxicology Consultant

44. Paragraph 44 is denied. In further response, with respect to Shayne Gad, Ph.D., a nationally recognized expert on toxicology, PSN Labs engaged Dr. Gad in June 2021 *after* obtaining approval from Philips to do so. Dr. Gad reviewed and provided commentary on the findings of three independent laboratories: PSN Labs, UL, and Intertek. Dr. Gad's conclusion was simple: the device should not be sold with the PE-PUR foam. With respect to his review of PSN Labs, Dr. Gad confirmed PSN Labs' assessment of dimethyl diazene. While Dr. Gad determined the toxicology threshold of concern for Phenol, 2,6-bis was different than that identified by PSN Labs, the tested device nevertheless failed under the recalculated threshold. Critically, Dr. Gad determined the PE-PUR foam was genotoxic, one of the most serious failings. Further, PSN Labs stated directly and repeatedly that the hazards had not been characterized and that further testing was recommended.

45. Paragraph 45 is denied. In further response, with respect to Shayne Gad, Ph.D., a nationally recognized expert on toxicology, PSN Labs engaged Dr. Gad in June 2021 *after* obtaining approval from Philips to do so. Dr. Gad reviewed and provided commentary on the findings of three independent laboratories: PSN Labs, UL, and Intertek. Dr. Gad's conclusion was simple: the device should not be sold with the PE-PUR foam. With respect to his review of PSN Labs, Dr. Gad confirmed PSN Labs' assessment of dimethyl diazene. While Dr. Gad determined the toxicology threshold of concern for Phenol, 2,6-bis was different than that identified by PSN Labs, the tested device nevertheless failed under the recalculated threshold. Critically, Dr. Gad determined the PE-PUR foam was genotoxic, one of the most serious failings. Further, PSN Labs stated directly and repeatedly that the hazards had not been characterized and why further testing was recommended.

B. Findings on Phenol

46. Paragraph 46 is denied. In further response, PSN Labs used multiple methods to risk assess Phenol, 2,6-bis, and in Rev E showed the progression of calculations as PSN Labs conducted additional research on the molecule. As PSN Labs' report confirms, "multiple conservative methods were used to risk assess the Phenol, 2,6-bis." PSN Labs did not say and/or write that Phenol, 2,6-bis was "mutagenic" or "a mutagen." What PSN Labs did say is that this specific molecule has a piece of its chemistry (its actual structure) that in many other molecules has caused those molecules to be genotoxic and/or mutagenic. Meaning, from a toxicological weight of evidence approach, classifying and risk assessing the molecule as having the potential to be genotoxic and/or mutagenic with accompanying appropriate thresholds is the proper course of action. While Dr. Gad determined the toxicology threshold of concern for Phenol, 2,6-bis was different than that identified by PSN Labs, the tested device nevertheless failed under the recalculated threshold. Critically, Dr. Gad determined the foam was genotoxic, one of the most serious failings, which confirmed Philips' own *in vivo* assays. Rarely is the science this clear and obvious, but in this case it was. Philips' purposefully ignored Dr. Gad's and its own conclusions in this regard, as was common of Philips with results that were failing or unfavorable. Further, PSN Labs stated directly and repeatedly that the hazards had not been characterized, which is why further testing was recommended.

47. Paragraph 47 is denied. In further response, PSN Labs used multiple methods to risk assess Phenol, 2,6-bis, and in Rev E showed the progression of calculations as PSN Labs conducted additional research on the molecule. As PSN Labs' report confirms, "multiple conservative methods were used to risk assess the Phenol, 2,6-bis." PSN Labs did not say and/or write that Phenol, 2,6-bis was "mutagenic" or "a mutagen." What PSN Labs did say is that this specific molecule has a piece of its chemistry (its actual structure) that in many other molecules

has caused those molecules to be genotoxic and/or mutagenic. Meaning, from a toxicological weight of evidence approach, classifying and risk assessing the molecule as having the potential to be genotoxic and/or mutagenic with accompanying appropriate thresholds is the proper course of action. Stated another way, the class of molecules, of which Phenol, 2,6-bis is a part, is known to have the ability to induce genotoxicity and mutagenicity -- rendering PSN Labs' statements in Rev E, F, and G entirely accurate.

48. Paragraph 48 is denied. In further response, PSN Labs is not concerned about its reputation with Philips. Further, PSN Labs used multiple methods to risk assess Phenol, 2,6-bis, and in Rev E showed the progression of calculations as PSN Labs conducted additional research on the molecule -- as PSN Labs' report confirms, "multiple conservative methods were used to risk assess the Phenol, 2,6-bis." PSN Labs did not say and/or write that Phenol, 2,6-bis was "mutagenic" or "a mutagen." What PSN Labs did say is that this specific molecule has a piece of its chemistry (its actual structure) that in many other molecules has caused those molecules to be genotoxic and/or mutagenic. Meaning, from a toxicological weight of evidence approach, classifying and risk assessing the molecule as having the potential to be genotoxic and/or mutagenic with accompanying appropriate thresholds is the proper course of action. Stated another way, the class of molecules, of which Phenol, 2,6-bis is a part, is known to have the ability to induce genotoxicity and mutagenicity -- rendering PSN Labs' statements in Rev E, F, and G entirely accurate. Further, the recall was not undertaken because the VOCs in the as-manufactured device were problematic, and any allegation that article circulation on Phenol, 2,6-bis impacted the recall is specifically denied. The recall took place because the PE-PUR foam degrades, as admitted by Philips on its own website. This was also discussed by the FDA: "the devices recalled by Philips contain a polyester-based polyurethane (PE-PUR) foam that may degrade into particles that may be ingested or inhaled by device users, and/or may emit volatile organize compounds

(VOCs) above acceptable thresholds, with potential toxic and carcinogenic effects and other significant harms." This is further supported because no FDA-approved studies were conducted to show under what circumstances the PE-PUR foam is safe across the useful lifetime of the device (*i.e.*, Philips repeatedly tested variables as opposed to testing the PE-PUR devices in any real-life setting).

49. Paragraph 49 is denied. In further response, PSN Labs used multiple methods to risk assess Phenol, 2,6-bis, and in Rev E showed the progression of calculations as PSN Labs conducted additional research on the molecule -- as PSN Labs' report confirms, "multiple conservative methods were used to risk assess the Phenol, 2,6-bis." PSN Labs did not say and/or write that Phenol, 2,6-bis was "mutagenic" or "a mutagen." What PSN Labs did say is that this specific molecule has a piece of its chemistry (its actual structure) that in many other molecules has caused those molecules to be genotoxic and/or mutagenic. Meaning, from a toxicological weight of evidence approach, classifying and risk assessing the molecule as having the potential to be genotoxic and/or mutagenic with accompanying appropriate thresholds is the proper course of action. Stated another way, the class of molecules, of which Phenol, 2,6-bis is a part, is known to have the ability to induce genotoxicity and mutagenicity -- rendering PSN Labs' statements in Rev E, F, and G entirely accurate. Further, the recall was not undertaken because the VOCs in the as-manufactured device were problematic, and any allegation that article circulation on Phenol, 2,6-bis impacted the recall is specifically denied. The recall took place because the PE-PUR foam degrades, as admitted by Philips on its own website. This was also discussed by the FDA: "the devices recalled by Philips contain a polyester-based polyurethane (PE-PUR) foam that may degrade into particles that may be ingested or inhaled by device users, and/or may emit volatile organize compounds (VOCs) above acceptable thresholds, with potential toxic and carcinogenic effects and other significant harms." This is further supported because no FDA-approved studies

were conducted to show under what circumstances the PE-PUR foam is safe across the useful lifetime of the device (*i.e.*, Philips repeatedly tested variables as opposed to the PE-PUR devices in any real-life setting).

C. Denied Concealment of Prior Mistakes

50. Paragraph 50 is denied. Again, Philips created the dimethyl diazene issue and, at Philips' request, PSN Labs issued Rev D to take a "more aggressive stance" on dimethyl diazene (the first time dimethyl diazene was at issue because PSN Labs had initially passed dimethyl diazene as "tentative" in Rev C). PSN Labs provided no explanation of its findings because there was nothing to report. PSN Labs did not conduct a full toxicological risk assessment having understood, and communicating to Philips, that a full risk assessment according to ISO 10993-17 or ISO 19562-1 could not be written for a device that is known to degrade. The device degrades – and violates ISO 10993-1:2018, clause 4.7, which requires the device to be biologically safe across its lifetime, so no risk assessment can be written. Further, it was never a singular compound that was an issue. It was the variability of the devices, the plurality of the VOCs, and the known fact that the foam within the device degrades as a function of normal use.

V. PSN Labs' Refusal to Return Philips Alleged Property

51. Paragraph 51 is denied. In further response, Section 5.1 of the 2019 Quality Agreement requires PSN Labs to conduct all Philips testing in accordance with ISO/IEC 17025, which in turn mandates that PSN Labs evaluate risks to impartiality on an on-going basis. PSN Labs encountered numerous red flags during Philips's repeated requests for the raw data that led PSN Labs to suspect that Philips might use the raw data to pressure PSN Labs to modify its report. Accordingly, PSN Labs denied Philips' raw data requests to preserve the impartiality of PSN Labs'

test reports and remain compliant with ISO/IEC 17025. Per the 2019 Quality Agreement, this mandate took precedence over any assertion that Philips was contractually entitled to the raw data. Further, VOC testing is not an *in vivo* or *in vitro* assay. It is a theoretical test that takes measured amounts of VOCs and applies safety factors to determine *potential* risks. No singular test can possibly be used to identify all risks to a patient, especially when the test is conducted in a way that does not mimic the way that the device is used in the field. The devices in question failed *in vivo* and *in vitro* tests before the recall, which clearly identified that a risk existed and needed to be investigated. The risks likely still have not been fully characterized, so to state that PSN Labs impacted this process in any way is patently false.

52. Paragraph 52 is denied. In further response, Section 5.1 of the 2019 Quality Agreement requires PSN Labs to conduct all Philips testing in accordance with ISO/IEC 17025, which in turn mandates that PSN Labs evaluate risks to impartiality on an on-going basis. PSN Labs encountered numerous red flags during Philips's repeated requests for the raw data that led PSN Labs to suspect that Philips might use the raw data to pressure PSN Labs to modify its report. Accordingly, PSN Labs denied Philips' raw data requests to preserve the impartiality of PSN Labs' test reports and remain compliant with ISO/IEC 17025. Per the 2019 Quality Agreement, this mandate took precedence over any assertion that Philips was contractually entitled to the raw data. Further, PSN Labs was advised by its accreditor (Perry Johnson Laboratory Accreditation, Inc. ["PJLA"]) that any further transfer of information (the "raw data" as alleged in Philips' Complaint) would be an infringement of clause 4.1 of ISO/IEC 17025:2017 related to impartiality. At the time of the request, PSN Labs was also advised during several exchanges with then-Philips employees that the request for raw data was Philips' attempt to change the compounds to more favorable results. Ultimately, it was PSN Labs that suggested Philips' subpoena the data.

53. Paragraph 53 is denied. In further response, Philips issued a supplier corrective action request (SCAR) on January 19, 2022. The SCAR was premised under Section 5.2 of the 2019 Quality Agreement which states, in part, PSN Labs "shall fully cooperate with all reasonable requests . . . ." Accordingly, on February 14, 2022, PSN Labs responded, and the SCAR was closed without further question. Further, the January 19, 2022 and February 14, 2022 communications are written documents that speak for themselves and PSN Labs denies any interpretation and/or characterization of their contents that is inconsistent with their express provisions.

54. Paragraph 54 is denied. In further response, and as communicated to Philips on multiple occasions, PSN Labs maintains a regular electronic data preservation policy of deleting or overwriting electronic data every six months. This deletion schedule applies to all raw data stored within the company's equipment, although anything developed for inclusion in reports is retained in perpetuity. PSN Labs' preservation policy was suspended, as appropriate, following receipt of a United States Department of Justice subpoena on September 14, 2022, related to Philips' devices. Accordingly, the oldest raw data that PSN Labs intentionally preserved, and which was available for production to DOJ and subsequently to Philips, was dated on or around mid-March 2021.

CLAIMS FOR RELIEF

COUNT I - CONTRACTUAL INDEMNIFICATION

55. PSN Labs incorporates Paragraph 1 through 54 of this Answer as though set forth at length herein.

56. Paragraph 56 is denied. In further response, Philips' General Conditions of Purchase is a written document that speaks for itself, and PSN Labs denies any interpretation

and/or characterization of its contents that is inconsistent with its express provisions. Further, it is denied that Philips is entitled to indemnification in any amount by or from PSN Labs. Strict proof thereof is demanded at time of trial.

57. Paragraph 57 is denied. In further response, Paragraph 57 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that Philips is entitled to indemnification in any amount by or from PSN Labs. Strict proof thereof is demanded at time of trial.

58. Paragraph 58 is denied. In further response, Paragraph 58 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that Philips is entitled to indemnification in any amount by or from PSN Labs. Strict proof thereof is demanded at time of trial.

59. Paragraph 58 is denied. In further response, Paragraph 58 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that Philips is entitled to indemnification in any amount by or from PSN Labs. Strict proof thereof is demanded at time of trial.

WHEREFORE, defendant PSN Labs, LLC respectfully requests that judgment be entered in its favor and against plaintiffs, Philips RS North America, LLC and Philips North America, LLC with respect to all claims set forth in the First Count (Contractual Indemnification) of the Complaint.

COUNT II - BREACH OF CONTRACT
(Alleged Failure to Provide Contractually Adequate Testing Services)

60. PSN Labs incorporates Paragraph 1 through 59 of this Answer as though set forth at length herein.

61. Paragraph 61 is denied. In further response, Paragraph 61 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement. Strict proof thereof is demanded at time of trial.

62. Paragraph 62 is denied. In further response, the 2019 Quality Agreement is a written document that speaks for itself, and PSN Labs denies any interpretation and/or characterization of its contents that is inconsistent with its express provisions. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement. Strict proof thereof is demanded at time of trial.

63. Paragraph 63 is denied. In further response, the 2019 Quality Agreement and the Philips' General Conditions of Purchase are written documents that speak for themselves, and PSN Labs denies any interpretation and/or characterization of their contents that is inconsistent with their express provisions. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. Strict proof thereof is demanded at time of trial.

64. Paragraph 64 is denied. In further response, Paragraph 64 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. Strict proof thereof is demanded at time of trial.

65. Paragraph 65 is denied. In further response, the ISO standards are written documents that speaks for themselves, and PSN Labs denies any interpretation and/or characterization of their contents that is inconsistent with their express provisions. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. Strict proof thereof is demanded at time of trial. In further response, Philips' inclusion of footnotes throughout the Complaint does not comply with Federal Rule of Civil Procedure 10(b), requiring that allegations be stated "in Numbered paragraphs, each limited as far as practicable to a single set of circumstances." As such, no response is required to the footnotes, and they would be properly stricken. *See Holmes v. Gates*, 2010 WL 956412, at *1 (M.D. Pa. Mar. 11, 2010), *aff'd.* 403 F. App'x 670 (3d Cir. 2010). To the extent that any response to footnote 7 of Paragraph 65 is required, the averment contained within this footnote is admitted.

66. Paragraph 66 is denied. In further response, Paragraph 66 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. Strict proof thereof is demanded at time of trial.

67. Paragraph 67 is denied. In further response, Paragraph 67 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Strict proof thereof is demanded at time of trial.

68. Paragraph 68 is denied. In further response, Paragraph 68 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN

Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. Strict proof thereof is demanded at time of trial.

69. Paragraph 69 is denied. In further response, Paragraph 69 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. It is further denied that the alleged breach of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

WHEREFORE, defendant PSN Labs, LLC respectfully requests that judgment be entered in its favor and against plaintiffs, Philips RS North America, LLC and Philips North America, LLC with respect to all claims set forth in the Second Count (Breach of Contract) of the Complaint.

COUNT III - BREACH OF CONTRACT
(Alleged Failure to Adequately Maintain Records)

70. PSN Labs incorporates Paragraph 1 through 69 of this Answer as though set forth at length herein.

71. Paragraph 71 is denied. In further response, Paragraph 71 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. Strict proof thereof is demanded at time of trial.

72. Paragraph 72 is denied. In further response, the Philips' General Conditions of Purchase is a written document that speaks for itself, and PSN Labs denies any interpretation

and/or characterization of its contents that is inconsistent with its express provisions. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. Strict proof thereof is demanded at time of trial.

73. Paragraph 73 is denied. In further response, the 2019 Quality Agreement and the ISO standards are written documents that speak for themselves, and PSN Labs denies any interpretation and/or characterization of their contents that is inconsistent with their express provisions. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement. Strict proof thereof is demanded at time of trial.

74. Paragraph 74 is denied. In further response, Paragraph 74 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. Strict proof thereof is demanded at time of trial.

75. Paragraph 75 is denied. In further response, Paragraph 75 states a conclusion of law and/or expert opinion to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. It is further denied that the alleged breach of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

76. Paragraph 76 is denied. In further response, Paragraph 76 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions

of Purchase. It is further denied that the alleged breach of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

77. Paragraph 77 is denied. In further response, Paragraph 77 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. It is further denied that the alleged breach of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

WHEREFORE, defendant PSN Labs, LLC respectfully requests that judgment be entered in its favor and against plaintiffs, Philips RS North America, LLC and Philips North America, LLC with respect to all claims set forth in the Third Count (Breach of Contract) of the Complaint.

COUNT IV - BREACH OF CONTRACT
(Alleged Failure to Return Philips' Property)

78. PSN Labs incorporates Paragraph 1 through 77 of this Answer as though set forth at length herein.

79. Paragraph 79 is denied. In further response, Paragraph 79 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. It is further denied that the alleged breach of certain conditions in the performance

of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

80. Paragraph 80 is denied. In further response, Paragraph 80 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. It is further denied that the alleged breach of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

81. Paragraph 81 is denied. In further response, Paragraph 81 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. It is further denied that the alleged breach of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

82. Paragraph 82 is denied. In further response, Paragraph 82 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. It is further denied that the alleged breach of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

83. Paragraph 83 is denied. In further response, Paragraph 83 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase. It is further denied that the alleged breach of certain conditions in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

WHEREFORE, defendant PSN Labs, LLC respectfully requests that judgment be entered in its favor and against plaintiffs, Philips RS North America, LLC and Philips North America, LLC with respect to all claims set forth in the Fourth Count (Breach of Contract) of the Complaint.

COUNT V - BREACH OF IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

84. PSN Labs incorporates Paragraph 1 through 83 of this Answer as though set forth at length herein.

85. Paragraph 85 is denied. In further response, Paragraph 85 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any implied covenant of good faith and/or fair dealing. It is further denied that the alleged breach of certain implied covenants in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

86. Paragraph 86 is denied. In further response, Paragraph 86 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any implied

covenant of good faith and/or fair dealing. It is further denied that the alleged breach of certain implied covenants in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

87. Paragraph 87 is denied. In further response, Paragraph 87 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any implied covenant of good faith and/or fair dealing. It is further denied that the alleged breach of certain implied covenants in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

88. Paragraph 88 is denied. In further response, Paragraph 88 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any implied covenant of good faith and/or fair dealing. It is further denied that the alleged breach of certain implied covenants in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

89. Paragraph 89 is denied. In further response, Paragraph 89 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any implied covenant of good faith and/or fair dealing. It is further denied that the alleged breach of certain implied covenants in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

WHEREFORE, defendant PSN Labs, LLC respectfully requests that judgment be entered in its favor and against plaintiffs, Philips RS North America, LLC and Philips North America,

LLC with respect to all claims set forth in the Fifth Count (Breach of Implied Covenant of Good Faith and Fair Dealing) of the Complaint.

COUNT VI - NEGLIGENCE

90. PSN Labs incorporates Paragraph 1 through 89 of this Answer as though set forth at length herein.

91. Paragraph 91 is denied. In further response, Paragraph 91 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs breached any agreement with Philips, including the 2019 Quality Agreement and/or Philips' General Conditions of Purchase, and/or that PSN Labs committed negligence in any respect. It is further denied that the alleged professional negligence in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

92. Paragraph 92 is denied. In further response, Paragraph 92 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs committed negligence in any respect. It is further denied that the alleged professional negligence in the performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

93. Paragraph 93 is denied. In further response, Paragraph 93 states a conclusion of law to which no response is necessary. To the extent that a response is deemed necessary, the averments therein are specifically denied. Further, it is denied that PSN Labs committed negligence in any respect. It is further denied that the alleged professional negligence in the

performance of services was the cause of the Philips' alleged injuries and/or damages. Strict proof thereof is demanded at time of trial.

WHEREFORE, defendant PSN Labs, LLC respectfully requests that judgment be entered in its favor and against plaintiffs, Philips RS North America, LLC and Philips North America, LLC with respect to all claims set forth in the Sixth Count (Negligence) of the Complaint.

A JURY TRIAL IS HEREBY DEMANDED.

AFFIRMATIVE DEFENSES

94. PSN Labs incorporates Paragraphs 1 through 93 above as though set forth at length herein.

First Affirmative Defense

95. Philips' Complaint fails to state a claim upon which relief can be granted.

Second Affirmative Defense

96. Philips' Complaint fails to state a sustainable claim for special, indirect, incidental and/or consequential damages against PSN Labs.

97. Indemnification for recall-related costs and expenses are not recoverable as special, indirect, incidental, and/or consequential damages as they are not reasonably foreseeable and/or not the natural and/or ordinary result of any purported breach of PSN Labs' scope of work.

Third Affirmative Defense

94. Philips' Complaint fails to state sustainable claims for punitive damages against PSN Labs.

Fourth Affirmative Defense

95. Philips' Complaint fails to state sustainable claims upon which an award of attorneys' fees and costs can be based.

Fifth Affirmative Defense

96. The claims against PSN Labs are barred, in whole or in part, by the doctrine of laches and/or the applicable Statute of Limitations.

97. In 2021, Philips criticized, attempted to revoke, attempted to modify, and/or attempted to create a second health hazard evaluation (HHE) upon the allegation that PSN Labs' results contained within the initial HHE were faulty and/or otherwise inaccurate.

98. Also in 2021, Philips attempted to revert and/or otherwise alter the scope of the recall, but the FDA refused to approve Philips' attempts and required that the recall remain a Class I recall as initiated in June 2021 and it remains so at present.

99. Despite these attempts in 2021, Philips waited until end of July 2024 to file the above-captioned matter against PSN Labs.

Sixth Affirmative Defense

100. The claims against PSN Labs are barred, in whole or in part, by estoppel, waiver, and/or unclean hands.

Seventh Affirmative Defense

101. If Philips sustained damages by reason of the matters alleged in the Complaint, which is denied, then said damages were caused in whole or in part by Philips' own breach of contract and fault and/or Philips' failure to properly design and/or manage its product (including use of non-medical grade foam) and/or product line (including failure to timely and appropriately address consumer complaints and/or take timely and appropriate action despite knowledge of degradation of devices containing PE-PUR foam), and were not caused or contributed to in any manner by any alleged fault, breach of contract, breach of warranty, or negligence of PSN Labs, its officers, agents, contractors, servants, employees, or others for whom it was responsible.

102. The claims against PSN Labs are barred, in whole or in party, by Philips' contributory negligence.

103. The claims against PSN Labs are barred and/or limited, in whole or in part, by Philips' comparative negligence.

Eighth Affirmative Defense

104. If Philips sustained damages as alleged in the Complaint, which is denied, said damages were caused solely by or contributed to by the acts and fault of third parties and were not caused or contributed to by any acts or fault of PSN Labs, its officers, agents, servants, employees, contractors, or others for whom they were responsible.

Ninth Affirmative Defense

105. If Philips sustained damages as alleged in the Complaint, which is denied, Philips has failed to mitigate its damages and any recovery is to be diminished by the degree of said failure to mitigate.

106. If Philips sustained damages as alleged in the Complaint, which is denied, Philips recovery is reduced by any amounts already received by Philips, from its insurers, affiliates, third-parties, or otherwise.

Tenth Affirmative Defense

107. At all times material to this action, the services rendered by PSN Labs were appropriate, timely, and in accordance with the 2019 Quality Agreement, the applicable standards in the professional community, and pursuant to PSN Labs' ISO accreditation.

Eleventh Affirmative Defense

108. The claims against PSN Labs are barred or limited, in whole or in part, by Section 5.1 of the 2019 Quality Agreement given PSN Labs' compliance with the Quality Management System requirements as set forth therein.

109. The claims against PSN Labs are barred or limited, in whole or in part, by Section 5.2 of the 2019 Quality Agreement given PSN Labs' compliance with maintenance of a corrective and preventative action (CAPA) system as set forth therein.

110. The claims against PSN Labs are barred or limited, in whole or in part, by Section 5.3 of the 2019 Quality Agreement given PSN Labs' compliance with document control measures as set forth therein.

Twelfth Affirmative Defense

111. The claims against PSN Labs are barred or limited, in whole or in part, by Section 6 of the 2019 Quality Agreement given PSN Labs' compliance with services control as set forth therein.

Thirteenth Affirmative Defense

112. The claims against PSN Labs are barred or limited, in whole or in part, by Section 7 of the 2019 Quality Agreement given PSN Labs' compliance with change control as set forth therein.

Fourteenth Affirmative Defense

113. The claims against PSN Labs are barred or limited, in whole or in part, by Section 8.1 of the 2019 Quality Agreement given PSN Labs' compliance with the Philips' audit procedures as set forth therein.

114. The claims against PSN Labs are barred or limited, in whole or in part, by Section 8.1 of the 2019 Quality Agreement given PSN Labs' compliance with the internal audit procedures as set forth therein.

Fifteenth Affirmative Defense

115. The claims against PSN Labs are barred or limited, in whole or in part, by Section 10 of the 2019 Quality Agreement given PSN Labs' compliance with the review procedures as set forth therein.

Sixteenth Affirmative Defense

116. The claims against PSN Labs are barred or limited, in whole or in part, by the economic loss doctrine.

Seventeenth Affirmative Defense

117. The claims against PSN Labs are barred or limited, in whole or in part, by the scope of the indemnification language and Philips' failure to adequately allege coverage (or indemnification) pursuant to same.

118. The claims against PSN Labs are barred or limited, in whole or in part, by the scope of the indemnification language and Philips' own negligence negating same.

Eighteenth Affirmative Defense

119. The claims against PSN Labs are barred or limited, in whole or in part, because PSN Labs is not governed by ISO 13485:2016 for testing lab activities, but instead by ISO/IEC 17025:2017. PSN Labs at all times complied with the standards as set forth by ISO/IEC 17025:2017.

Nineteenth Affirmative Defense

120. The claims against PSN Labs are barred or limited, in whole or in part, as Philips had an opportunity to audit PSN Labs, including personnel and equipment. Further, PSN Labs is annually audited by its registrar (PJLA). PSN Labs has had zero minor or major non-conformances (NCRs), Corrective Action Requests (CARs), or Opportunities for Improvement (OFIs) for ISO 18562 testing from its registrar and/or Philips.

Twentieth Affirmative Defense

121. The claims against PSN Labs are barred or limited, in whole or in part, as PSN Labs recommended to Philips that Philips contact the FDA to help address management and scope concerns related to the then-contemplated recall of devices. Philips failed to timely follow PSN Labs' recommendation.

Twenty-First Affirmative Defense

122. The claims against PSN Labs are barred or limited, in whole or in part, due to Philips' failure to perform its obligations pursuant to the 2019 Quality Agreement, including:

a. Philips' failure to inform PSN Labs that it was being asked to test devices that had failed multiple rounds of biocompatibility tests (as early as 2008) -- it is unethical to continue to test devices seeking "passing" results, and had PSN Labs known of the previous biocompatibility test failures, it would have declined the work pursuant to Philips' purchase orders;

b. Philips failure to inform PSN Labs of the intent of the testing (which was, as later learned, to support a post-market risk assessment [PMRA] and potential recall); and

c. Philips repeated failure to be truthful and/or factual in communications with PSN Labs related to the services requested.

Twenty-Second Affirmative Defense

123. The claims against PSN Labs are barred or limited, in whole or in part, as PSN Labs suggested additional testing to address the PE-PUR foam degradation, but Philips refused.

Twenty-Third Affirmative Defense

124. Philips incredulously alleges that it relied upon only one report of PSN Labs (70025-RP-01, Rev G) issued on July 29, 2021 (more than a month after the recall began) to initiate a recall of over 15 million devices and would have done so differently if not for PSN Labs' errors.

125. The U.S. Food and Drug Administration identified approximately 222,000 complaints that were improperly classified by Philips and all of which related to PE-PUR foam degradation prior to PSN Labs commencing services in 2021 -- a clear sign there was a problem with the device prior to any testing by PSN Labs.

126. The U.S. Food and Drug Administration also identified a 2019 corrective and preventative action (CAPA) following multiple failed VOC tests and failed genotoxicity and sensitization testing -- again, prior to any services performed by PSN Labs.

127. The failed genotoxicity and cytotoxicity testing are two assays that alone are enough to trigger a recall -- and again known to Philips prior to any services performed by PSN Labs.

128. Upon information and belief, Philips' own employees were calling for a recall no later than 2020 -- and yet again, prior to any services and/or findings of PSN Labs.

129. Prior to PSN Labs testing, the PE-PUR foam had already tested positive for cytotoxicity, tested positive for genotoxicity, and had failed out-of-the-box VOC testing.

130. Accordingly, PSN Labs had no impact on the recall as alleged.

RESERVATION TO ASSERT ADDITIONAL AFFIRMATIVE DEFENSES

131. PSN Labs reserves the right to assert additional defenses to the claims set forth in the Complaint at such time and to such extent as is warranted by pretrial discovery or other

developments in this civil action and/or as otherwise permitted by law, rule, and/or this Honorable Court.

WHEREFORE, defendant PSN Labs, LLC respectfully requests that judgment be entered in its favor and against plaintiffs, Philips RS North America, LLC and Philips North America, LLC with respect to all claims set forth in the Complaint.

A JURY TRIAL IS HEREBY DEMANDED.

Respectfully submitted,
s/ Jamie R. Schumacher

W. Patrick Delaney
William S. Speros
Jamie R. Schumacher
MacDONALD, ILLIG, JONES & BRITTON LLP
100 State Street, Suite 700
Erie, Pennsylvania 16507-1459
(814) 870-7613
(814) 454-4647 (facsimile)
wdelaney@mijb.com
wsperos@mijb.com
jschumacher@mijb.com

Attorneys for Defendant,
PSN Labs, LLC

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CERTIFICATE OF SERVICE

I certify that on September 27, 2024, the foregoing Answer and Affirmative Defenses, was filed electronically with the Clerk of Court, using the CM/ECF system. Notice of this filing will be sent to all parties who have appeared of record by operation of the Court's ECF system and constitutes service of this filing under Rule 5(b)(2)(E) of the Federal Rules of Civil Procedure. Those parties may access this filing through the Court's ECF system.

s/ Jamie R. Schumacher
Jamie R. Schumacher